WHAT IS CLAIMED IS:

1. Crude lercanidipine hydrochloride solid Form (A), having a melting point of about 150-152°C (DSC peak) and comprising about 3-4% (w/w) ethyl acetate.

2. Crude lercanidipine hydrochloride solid Form (B), having a melting point of about 131-135°C (DSC peak) and comprising about 0.3-0.7% (w/w) ethyl acetate.

3. A method of producing the crude lercanidipine hydrochloride Form of claim 1, comprising the steps of:

a) reacting 2,6-dimethyl-5-methoxycarbonyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3-carboxylic acid with a chloride selected from the group consisting of thionyl chloride and oxalyl chloride in an aprotic dipolar solvent and an aprotic polar solvent to produce the corresponding carbonyl chloride;

b) reacting, *in-situ*, the chloride of step a) with 2, N-dimethyl-N-(3,3-diphenylpropyl)-1-amino-2-propyl alcohol to form crude lercanidipine hydrochloride; and

c) isolating the crude lercanidipine hydrochloride of step b and recovering crude lercanidipine hydrochloride Form (A).

4. The method of claim 3 wherein the reacting step b) is conducted at a temperature between -5 and +5°C.

5. The method of claim 3 wherein step c) comprises the steps of:

i) washing the crude lercanidipine hydrochloride of step b) with water;

ii) removing the water from step i) to produce a mixture;

iii) concentrating the mixture of step ii) and adding solvent to produce a suspension having about the same volume as the initial volume of the mixture of step ii) and a water content, according to Karl Fischer, of between 0.10 and 0.15%;

iv) cooling the suspension obtained in step iii) to obtain a solid;

v) filtering the solid from step iv);

vi) re-suspending the solid of step v) in ethyl acetate;

vii) cooling the suspension of step vi) ; and

viii) filtering and drying the precipitate of step vii) to produce the crude lercanidipine hydrochloride Form (A).

6. The method of claim 3 wherein the chloride in step a) is thionyl chloride.

7. The method of claim 5 wherein step c) ii) comprises removing the water from step c) i) by azeotropic distillation under vacuum within the range 200-300 mm Hg, at a temperature not higher than 60°C, to produce a mixture.

8. The method of claim 5 wherein the resuspending step vi) comprises stirring at 60-65°C for about 1 hour.

9. The method of claim 5 wherein the drying in step viii) is in an oven at 70°C.

10. The method of claim 5, wherein the washing step i) is with water; the mixture in step iii) is concentrated to 1/3 of its initial volume and solvent is added to produce a suspension having about the same volume as the initial volume of said mixture;

and the water content of said suspension according to Karl Fischer , is between 0.1 and 0.15%.

11. The method of claim 5, wherein cooling in step iv) is to a temperature within the range of 0-5◦C.

12. The method of claim 5 wherein cooling in step vii) is to a temperature within range of 5-10°C.

13. A method of producing the crude lercanidipine hydrochloride Form of claim 2, comprising the steps of:

a) reacting 2,6-dimethyl-5-methoxycarbonyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3-carboxylic acid with a chloride selected from the group consisting of thionyl chloride and oxalyl chloride in an aprotic dipolar solvent and an aprotic polar solvent to produce the corresponding carbonyl chloride;

b) reacting, *in-situ*, the chloride of step a) with 2, N-dimethyl-N-(3,3-diphenylpropyl)-1-amino-2-propyl alcohol to yield crude lercanidipine hydrochloride; and

c) isolating the crude lercanidipine hydrochloride of step b) and recovering crude lercanidipine hydrochloride Form (B).

14. The method of claim 13 wherein the reacting step b) is conducted at a temperature between -5 and +5°C.

15. The method of claim 13 wherein step c) comprises the further steps of:

i') washing the crude lercanidipine hydrochloride of step b) with water,

ii') removing the water from step i') to produce a mixture having a water content of about 2%, measured according to Karl Fischer;

iii') concentrating the mixture of step ii') and adding solvent to produce a solution having about the same volume as the initial volume of the mixture of step ii') and a water content, according to Karl Fischer, of between 0.9 and 1.1%;

iv') cooling the solution of step iii') to obtain a solid;

v') filtering the solid of step iv');

vi') re-suspending the solid of step v') in a solvent;

vii') cooling the suspension of step vi'); and

viii') filtering and drying the solid obtained to produce the crude lercanidipine hydrochloride Form (B).

16. The method of claim 13 wherein the chloride is thionyl chloride.

17. The method of claim 15 wherein step c) ii') comprises removing the water from step i') by azeotropic reflux to produce said mixture.

18. The method of claim 15 wherein step c) iii') comprises concentrating said mixture to 3/4 of its initial volume.

19. The method of claim 15 wherein said solvent in steps c) iii') and vi') is ethyl acetate.

20. The method of claim 15 wherein the step c) iv') comprises cooling the solution to a temperature within the range of 0-5°C.

21. The method of claim 15 wherein said step c) vi') further comprises stirring the suspension at 60-65°C for about one hour.

22. The method of claim 21 wherein said step c) vii') further comprises cooling the solid to a temperature between 5 and 10°C.

23. The method of claim 15 wherein said drying in step viii') is in an oven at approximately 70°C.

24. The method of any one of claims 1-7, wherein said aprotic dipolar solvent is dimethylformamide and said aprotic polar solvent is ethyl acetate.

25. Isolated lercanidipine hydrochloride crystalline Form (I), which has the X-ray diffraction pattern, at wavelength Kα, as shown in Figure 11.

26. The lercanidipine crystalline Form of claim 10, wherein distances, (I/Io) ratios, and 2 θ angles of significant peaks in Figure 11 are:

D (Å)	Relative intensity (I/Io)	2 θ angle
16.3	83	5.4
6.2	47	14.2
4.78	29	18.6
4.10	63	21.7
4.06	36	21.9
3.90	100	22.8

27. Isolated lercanidipine hydrochloride crystalline Form (II), which has an X-ray diffraction pattern, at wavelength Kα, as shown in Figure 12.

28. The lercanidipine crystalline Form of claim 27, wherein distances, (I/Io) ratios, and 2 θ angles of significant peaks in Figure 12 are:

D (Å)	Relative intensity (I/Io)	2 θ angle
9.3	35	9.5
6.0	45	14.7
5.49	65	16.1

4.65	52	19.1
4.27	74	20.8
3.81	41	23.4
3.77	100	23.6
3.58	44	24.8
3.54	29	25.2

29. A method of producing lercanidipine hydrochloride crystalline Form (I), which has an X-ray diffraction pattern, at wavelength Kα, as shown in Figure 11, which comprises:

d) adding a C1-C5 alcohol solvent containing a maximum of 5% water (v/v) to a crude lercanidipine hydrochloride Form and heating under reflux and with stirring to produce a clear solution;

e) cooling the solution of step d) and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is ≤2%; and

f) recovering the solid obtained from step e), and drying said solid to produce the lercanidipine hydrochloride crystalline Form (I).

30. The method of claim 29, wherein step f) comprises filtering the solid obtained from step e), washing the solid with isopropanol and re-filtering the solid before drying.

31. The method of claim 29 wherein the alcohol of step d) is selected from the group consisting of isopropanol, ethanol and anhydrous ethanol.

32. The method of claim 29, wherein the crude Form is lercanidipine hydrochloride crude Form (A), lercanidipine hydrochloride crude Form (B) or lercanidipine crude Form (C)

33. The method of claim 29 wherein said step d) further comprises filtering the heated solution.

34. The method of claims 29 wherein said step e) comprises cooling the solution to a temperature between 30 and 40°C.

35. The method of claim 34 wherein said step e) further comprises stirring for a period of time of 12-48 hours.

36. The method of claim 29 wherein said drying in step f) takes place in an oven.

37. A method of producing lercanidipine hydrochloride crystalline Form (II), which has an x-ray diffraction pattern, at wavelength Kα, as shown in Figure 12, the method comprising the steps of:

d") adding acetonitrile to lercanidipine hydrochloride and heating the mixture thus obtained to form a solution;

e") cooling of the solution of step d") and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is ≤2%; and

f") recovering the solid of step e") and drying said solid to produce the lercanidipine hydrochloride Form (II).

38. The method of claim 37 wherein said step d") comprises heating said mixture under reflux with stirring.

39. The method of claim 37 wherein said step e") comprises cooling the solution to room temperature.

40. The method of claim 39 wherein said step e") comprises stirring the solution at room temperature for 24 hours.

41. The method of claim 37 wherein drying step f') takes place in an oven.

42. The method of claim 37, wherein the crude Form is lercanidipine hydrochloride crude Form (A), lercanidipine hydrochloride crude Form (B) or lercanidipine crude Form (C).

43. A method of producing lercanidipine hydrochloride crystalline Form (I), which has an x-ray diffraction pattern, at wavelength Kα, as shown in Figure 12, which comprises:

d') providing a mixture of ethanol and lercanidipine hydrochloride, refluxing under stirring and cooling and adding crystalline seeds of Form (I);

e') further cooling the seeded mixture of step d') and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is ≤2%; and

f') recovering the solid of step e') to form lercanidipine hydrochloride Form (I).

44. The method of claim 43 wherein the ratio of lercanidipine hydrochloride to volume of solvent in step d') on a weight volume ratio is within the range of about 1:4 to 1:6.

45. The method of claim 44 wherein said ratio is 1:4.

46. The method of claim 43 wherein said step d') further comprises filtering the heated solution.

47. The method of claim 43 wherein cooling in said step d') is to a temperature of 20°C while stirring.

48. The method of claim 43 wherein cooling in said step e') is to a temperature between 10 and 15°C.

49. The method of claim 43 wherein the drying in said step f') takes place in an oven at 70°C.

50. The method of claim 47 wherein authentic seeds of lercanidipine Form (I) are added at the end of cooling in steps e') and d').

51. A method of producing lercanidipine hydrochloride crystalline Form (II), which has an X-ray diffraction pattern, at wavelength K , as shown in Figure 12, which comprises:

d''') adding ethanol or isopropanol with a water content below 10% by weight to lercanidipine hydrochloride and refluxing to produce a solution;

e''') cooling the solution and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is $\leq 2\%$; and

f''') recovering the solid produced in step e''') to produce lercanidipine hydrochloride Form (II).

52. The method of claim 51 wherein ethanol is added in said step d''').

53. The method of claims 51 wherein the water content of the solvent in step d''') is between 5 and 10%.

54. The method of claim 51 wherein cooling in said step e''') is to a temperature between 20 and 40°C.

55. The method of claim 51 wherein step f''') comprises filtering said solid and drying in an oven.

56. A method of producing the lercanidipine hydrochloride crystalline Form (II), which has an x-ray diffraction pattern, at wavelength Kα, as shown in Figure 12, which comprises:

d'''') dissolving crude lercanidipine hydrochloride or lercanidipine hydrochloride crystalline Form (I) in a protic polar or an aprotic dipolar solvent containing up to 50% by weight of water to produce a solution;

e'''') stirring the solution of step d'''') until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is ≤2%; and

f'''') recovering the solid of step e'''') to produce lercanidipine Form (II).

57. The method of claim 56, further comprising irradiating with ultrasound and/or adding crystalline seeds of Form (II) to step e'''').

58. The method of claim 56, further comprising adding up to 60% water to the solution of step d'''').

59. The method of claim 56, wherein the protic polar solvent is an alcohol solvent.

60. The method of claim 56, wherein the alcohol solvent is selected from the group consisting of methanol, ethanol, n-propanol, isopropanol.

61. The method of claim 56, wherein the aprotic dipolar solvent is N-methyl-pyrrolidone.

62. The method of claim 56, wherein the temperature of said step d'''') is between 20 and 70°C.

63. The method of claim 56, wherein stirring in said step e'''') takes place at a temperature between 20 and 25°C.

64. The method of claim 56, wherein drying in said step f"") takes place at 70°C.

65. An antihypertensive pharmaceutical composition comprising (1) crystalline lercanidipine hydrochloride and optionally other forms of lercanidipine, wherein the crystalline lercanidipine hydrochloride is selected from the group consisting of lercanidipine hydrochloride crystalline Form (I), lercanidipine hydrochloride crystalline Form (II), and combinations thereof comprising a predetermined content of each crystalline form, and (2) at least one component selected from the group consisting of a pharmaceutically acceptable carrier or diluent, a flavorant, a sweetener, a preservative, a dye, a binder, a suspending agent, a dispersing agent, a colorant, a disintegrant, an excipient, a lubricant, a plasticizer, and an edible oil..

66. A unit dosage form comprising the antihypertensive pharmaceutical composition of claim 65.

67. The unit dosage form of claim 66 wherein the dosage form is a lercanidipine immediate release dosage form.

68. The unit dosage form of claim 66 wherein the dosage form is a lercanidipine controlled release dosage form.

69. The unit dosage form of claim 66 wherein the dosage form comprises a lercanidipine immediate release phase and a lercanidipine controlled release phase.

70. The unit dosage form of claim 66, wherein the composition comprises 0.1 to 400 mg lercanidipine hydrochloride.

71. The unit dosage form of claim 70, wherein the composition comprises 1 to 200 mg lercanidipine hydrochloride.

72. The unit dosage form of claim 71, wherein the composition comprises 5 to 40 mg lercanidipine hydrochloride.

73. A method of treating a subject with hypertension, coronary heart disease or congestive heart failure the method comprising administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (I), lercanidipine hydrochloride crystalline Form (II), or combinations thereof to a subject in need of such treatment.

74. A method of treating or preventing atherosclerotic lesions in arteries in a subject, which comprises administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (I), lercanidipine hydrochloride crystalline Form (II), or combinations thereof having a predetermined content in each of said Form I and II to a subject in need of such treatment.

75. A method of treating or preventing heart failure in a subject, which comprises administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (I), lercanidipine hydrochloride crystalline Form (II), or combinations thereof having a predetermined content in each of said Form I and II to a subject in need of such treatment.

76. The method of any one of claims 73 - 75 wherein said subject in need is a mammal.

77. The method of claim 76 wherein said subject is a human.

78. An antihypertensive composition comprising predetermined amounts of lercanidipine hydrochloride crystalline Form (I) and lercanidipine hydrochloride crystalline Form (II).

79. The antihypertensive composition of claim 78 wherein the lercanidipine hydrochloride crystalline Form (I) has a melting point of about 197-201 °C and the lercanidipine hydrochloride crystalline Form (II) has a melting point of about 207-211 °C, when said melting points are determined as DSC peaks.

80. The antihypertensive composition of claim 78 or claim 79 wherein the ratio of Form (I) : Form (II) is between 1:9 to 9:1.

81. The antihypertensive composition of claim 78 wherein the ratio of Form (I) : Form (II) is selected from the group consisting of 9:1, 7:3, 1:1, 3:7 and 1:9.

82. The isolated lercanidipine crystal Form of any one of claims 25, 26, 27 or 28 comprising an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.

83. The antihypertensive pharmaceutical composition of claim 65 wherein said lercanidipine hydrochloride crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.

84. The antihypertensive composition of claim 78 wherein said lercanidipine crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.